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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,237	11/10/2000	Philip Henry Coelho	30195-pa	3030
37095	7590	03/18/2004	EXAMINER	
BERNHARD KRETEN, ESQ & ASSOCIATES 1331 GARDEN HIGHWAY SUITE 300 SACRAMENTO, CA 95833			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/709,237

Applicant(s)

COELHO ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 10, 14 and 17-19 is/are ~~allowed~~ *free of art*.
- 6) ☒ Claim(s) 11, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-12 and 14-19 are pending.

Applicants' amendment filed December 15, 2003 is acknowledged. Applicant's response has been fully considered. Claims 9-11 have been amended, and new claims 14-19 have been added. Claims 1-8 and 12 are non-elected inventions, thus withdrawn from consideration. Therefore, claims 9-11 and 14-19 are examined.

Regarding the issue of rejoining the method claims (claims 1-8 and 12) with the product claims, please see the following paragraphs:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

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103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Objection Withdrawn

2. The previous objection of claim 11 is withdrawn in view of applicant's amendment to the claim in the amendment filed December 15, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

3. The previous rejection of claim 9 under 35 U. S. C. 101, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 5 in the amendment filed December 15, 2003.

Claim Rejections - 35 USC § 112

4. The previous rejection of claim 9 under 35 U. S. C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 5-6 in the amendment filed December 15, 2003.

Claim Rejections - 35 USC § 102

5. The previous rejection of claim 10 under 35 U. S. C. 102(b) as being anticipated by Regan *et al.* (U. S. Patent 5,674,482, filed August 9, 1991), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 6-7 in the amendment filed December 15, 2003.

Claim Rejections - 35 USC § 103

6. The previous rejection of claim 10 under 35 U. S. C. 103(a) as being unpatentable over Reid *et al.* (U. S. Patent 5,476,771, December 19, 1995) taken with Gustafesson *et al.* (U. S. Patent 5,965,692, priority date Dec. 17, 1996), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 7-9 in the amendment filed December 15, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11, 15 and 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 11 and 15 are indefinite because of the use of the term "both by volume" or "by volume". The term "both by volume" or "by volume" renders the claim indefinite, it is not clear

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how the concentration of CaCl_2 , which is cited as $0.023 \mu\text{M}$ or about $0.011\text{-}0.045 \mu\text{M}$, can be prepared by volume. Deletion of the term is suggested.

9. Claim 16 is indefinite because of the use of the term "less than about five seconds" or "at least about 240 minutes". The term "less than about five seconds" or "at least about 240 minutes" renders the claim indefinite, it is not clear whether the clotting time is shorter than 5 seconds as to "less than", or greater than 5 seconds as to "about"; and whether the thrombin is stable more than 240 minutes as to at least, or less than 240 minutes as to "about". Use the terms "about five seconds or less" and "about 240 minutes or greater" is suggested.

Conclusion

7. Claims 11, 15 and 16 are rejected, it appears claims 9, 10, 14 and 17-19 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

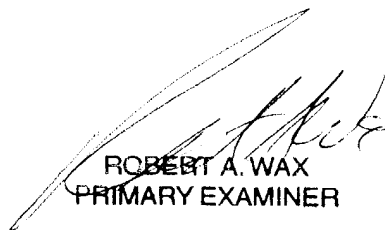
Chih-Min Kam, Ph. D. *C17K*
Patent Examiner

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March 13, 2004



ROBERT A. WAX
PRIMARY EXAMINER